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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,213	01/12/2007	Henrike Lotz	P/2107-299	5911

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OSTROLENK FABER GERB & SOFFEN
1180 AVENUE OF THE AMERICAS
NEW YORK, NY 100368403

EXAMINER	
TSAY, MARSHA M	

ART UNIT	PAPER NUMBER
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,213	LOTZ ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-38 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-2, 37, drawn to a *C. albicans* cell containing a vector in which a nucleic acid molecule which encodes a cell wall protein necessary for the hyphae development of a pathogenic fungal organism is arranged in antisense orientation to at least one regulation element and is selected from the group consisting of: (a) to (e).

Group II, claim(s) 3-4, 30-31, drawn to an antibody which recognizes a protein and binds thereto, wherein the protein contains an amino acid sequence selected from the group consisting of SEQ ID NOS: 2, 4, and 6.

Group III, claim(s) 5-12, drawn to a method for at least one of the characterization of and the detection of the hyphae stage of *Candida* cells or cells of pathogenic fungal organisms of a *Trichosporon* species or of a *Blastoschizomyces* species, the method comprising incubating the cells with an agent that recognizes a cell wall protein containing the sequence selected from SEQ ID NOS: 2, 4, and 6.

Group IV, claim(s) 13-21, drawn to a method for at least one of the detection of a *Candida* infection and of an infection by pathogenic fungal organisms of a *Trichosporon* species or of a *Blastoschizomyces* species in a biological sample, wherein the presence of at least one protein recited in said claim 13 is detected, the method comprising the steps of (a) to (b).

Group V, claim(s) 22, drawn to a method for the discovery and identification of substances having therapeutic action against diseases which are caused by *Candida* species or pathogenic fungal *Trichosporon* or *Blastoschizomyces* species, wherein a substance to be tested is brought into contact with at least one agent, and wherein the agent is selected from the group consisting of nucleic acid selected from (a) to (e), a vector, a host cell, a protein (SEQ ID NOS: 2, 4, 6), and an antibody to SEQ ID NOS: 2, 4, 6.

Group VI, claim(s) 23-24, drawn to a composition comprising an agent as identified in claim 22.

Group VII, claim(s) 25, 28-29, drawn to a composition in the form of a protein vaccine as identified according to claim 22.

Group VIII, claim(s) 26-27, drawn to a composition in the form of an antibody vaccine as identified according to claim 22.

Group IX, claim(s) 32, drawn to a method for the diagnosis of diseases in a human or animal organism which are caused by *Candida* species or pathogenic fungal organisms of a *Trichosporon* species or of a *Blastoschizomyces* species which comprises administering to said organism an agent as identified in claim 22.

Group X, claim(s) 33, drawn to a method for the production of a diagnostic composition comprising incorporating into said diagnostic composition a therapeutic substance as identified in claim 22.

Group XI, claim(s) 34, drawn to a method for the treatment of a disease caused by *Candida* species or pathogenic fungal organisms of *Trichosporon* species or of a *Blastoschizomyces* which comprises administering to an organism, a composition compressing an active material as identified in claim 22.

Group XII, claim(s) 35, drawn to a method for the production of a pharmaceutical composition comprising incorporating into said pharmaceutical composition a substance as identified in claim 22.

Group XIII, claim(s) 36, drawn to a method for at least one of the identification and the detection of a substance which inhibit the expression of the Rbr1p protein, wherein said substance is identified or detected with the use of a material identified by claim 22.

Group XIV, claim(s) 38, drawn to a method for at least one of the characterization and the detection of the virulent hyphae stage of *Candida* cells, wherein said method involves the use of an antibody that binds to a protein with the sequence of SEQ ID NOS: 2, 4, or 6.

The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-XIV appears to be a *Candida albicans* cell wall.

However, Sohn et al. (2003 2003 Molecular Microbiology 47(1): 89-102; IDS) teach a *C. albicans* cell wall.

Therefore, the technical feature linking the inventions of Groups I-XIV does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art.

Additionally, each group named above is subject to further restriction. Applicants are required to further elect a specific SEQ ID NO. This is NOT an election of species. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such sequence is presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the Examiner in his/her action shall require the Applicant…to elect that invention to which his claim shall be restricted." 37 C.F.R. 1.142(a). See also 37 C.F.R. 1.141(a). It is noted that searching more than one of the claimed patentably distinct sequences represents a serious burden for the Office.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Trichosporon, Blastoschizomyces (claims 5, 13, 22, 30, 32, 33, 34, 35);

C. albicans, C. tropicalis, C. krusei, C. parapsilosis, C. guilliermondi, C. glabrata, C. dubliniensis, C. lusitaniae (claims 6, 14, 37);

skin membrane swab, mucous membrane swab, organ biopsy, tissue biopsy, body fluid, body secretion, stool, rinse from a cavity, rinse from a hollow organ (claim 15);

sputum, urine, pleural effusion, spinal fluid, lymph, blood (claim 16);

unpurified blood sample, blood plasma, blood serum (claim 17);

dye label, radiolabel, fluorescent label, chemiluminescent label, enzyme inducing a measurable reaction (claim 21);

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 5, 13, 22, 37.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each of the species noted above are chemically and structurally different, and therefore, will have distinct properties and functions.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so**

may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

March 11, 2009